Minutes

LRC Study Committee on Pathological Materials

December 5, 2012
3:30 p.m. Room 544 LOB

The LRC Study Committee on Pathological Materials was called to order by Representative Tom Murry at 3:30 p.m. Members present at the meeting were Representative William Brisson, Representative Chuck McGrady, Representative Sarah Stevens, Senator Andrew Brock, Senator Thom Goolsby, Senator Louis Pate and Senator William Purcell. Also present were staff members Susan Barham, Amy Jo Johnson, Bill Patterson and Barbara Riley; Committee Clerk Joseph Kyzer; Senate Sergeant-at-Arms Billy Fritscher and Anderson Meadows and House Sergeant-at-Arms Young Bae and Martha Gadison.

Rep. Murry, serving as Chairman of the meeting, introduced himself and thanked everyone for attending. He acknowledged the Sergeant-at-Arms and said the meeting would start with a summary of the issue before the committee from Research Division staff member Bill Patterson

Committee Charge

Bill Patterson thanked Rep. Murry and said he would explain what the committee is set up to do. He reviewed an August 23, 2012, committee authorization letter from Senator Tom Apodaca and Representative Tim Moore, cochairmen of the Legislative Research Commission (LRC). That letter is provided as an attachment to these minutes. He added that the committee is required under LRC rules to transmit any final report with recommendations to the LRC cochairmen no later than January 4, 2013. He gave a summary of House Bill 795, listed its sponsors and reviewed its legislative history. A copy of the third edition of that bill is attached to these minutes.

Mr. Patterson said that in brief, this bill requires that a health care provider must furnish specified pathological materials collected from the patient and all other medical records of the patient within 30 days of receiving a written authorization signed by the patient or the patient's attorney, attorney in-fact, legal guardian, or in the case of a deceased patient, a personal representative of the deceased patient's estate. The statute defines pathological materials as including psychological materials, bodily fluids, tissues, organs, medical waste, paraffin blocks, pathology slides and the pathology report. The bill would have permitted the provider to charge a reasonable fee for producing a record pursuant to G.S. 90-411. It also would have required any materials to be transferred in accordance with best medical practices. It would have prohibited the release of materials in any manner that would endanger public health or welfare, or that would violate applicable laws and regulations pertaining to the safe handling and transfer of

pathological materials. The bill would not have applied to pathological materials collected as evidence of a crime or paternity. It would not have changed or interfered with best practices and accepted medical standards of the health care provider.

Mr. Patterson said he was finished with the summary and Rep. Murry asked if anyone had questions for him about the staff summary. There were no questions.

Rep. Murry said the committee would hear from interested parties and try to balance 25 minutes per side. He asked representatives of the N.C. Hospital Association to make their comments first.

Presentations

Hugh Tilson, the Senior Vice President of the N.C. Hospital Association, said he was presenting on behalf of North Carolina's 110 acute care hospitals. He said he wanted to run briefly through materials in the committee notebooks. He said the document called 'North Carolina Hospital Association Best Practices Principles' was most important and noted it was from him and dated December 4, 2012. A copy of that document is attached to these minutes. Mr. Tilson said at the end of the session this year he was made aware of concerns about patient access to pathological specimens, specifically the process by which an attorney for a patient could seek entire copies of pathological specimens. That was the issue causing many of the problems.

Mr. Tilson said that in the interim they pulled together a group of hospital lawyers and a group of pathologists to try and build on what they believe are the best practices in terms of specimen retention, compliance with federal guidelines, patient care, risk management and things delineated in the committee charge. He has heard from a number of hospitals about the practices they already use and what he thought was most helpful was to clearly articulate the principles upon which for individual hospitals, actual practices and procedures should be based.

He said these are based on best practices already being used in many facilities. Upon discussion today he will get the practices to the remainder of the hospitals in North Carolina to encourage their specific practices apply to these general principles. He said their goal is to make sure everyone knows what the general operating principle should be in terms of access to records, access to original slides, access to recuts and all those other types of issues. He said he would not read through the principles because they were included in committee notebooks, but he reviewed the general categories.

Mr. Tilson said the number one issue his association is looking to balance is compliance with federal regulations about how hospitals must retain samples. They want to work with those interested in getting access to those samples, make sure their attorneys and representatives can work with hospitals to get the information they need from those samples and get recuts of those samples. But in terms of the actual, original samples themselves, his association believes that all

conversations with national and other experts indicate they are required to maintain those on their premises.

He repeated that the N.C. Hospital Association has presented best practices that clearly articulate the expectations. If people are interested in availing themselves of recuts, of information or documentation, they would know what their practices or procedures would look like. Other experts can provide more meat on those bones, but generally that is the goal of the hospital association. To make sure that those expectations and practices were clear and distributed to hospitals throughout North Carolina to facilitate compliance with these principles.

Rep. Murry thanked Mr. Tilson and asked if anyone had questions for him about the issue. He noted there may be other questions for Mr. Tilson after everyone has a chance to present. Mr. Tilson thanked the committee, and Rep. Murry said Doug Herron from Duke University would make an introduction of the next presenter.

Mr. Herron thanked Rep. Murry and the committee for the opportunity to contribute. He introduced himself as the Director of Government Relations for Duke University Health Systems. In the interest of time, he gave his time allotted on the agenda to Dr. Shannon McCall, a pathologist at Duke University. He said she can give a step-by-step explanation of how cases are handled at Duke when these situations arise.

Dr. McCall thanked Doug Herron, the committee chairs and members for the opportunity to speak on an issue close to her heart. She introduced herself as the Quality Assurance Officer for the pathology practice at Duke University Medical Center. As such, she is quite familiar with the federal regulations that surround the areas on the issue today. She is also a practicing gastrointestinal pathologist. She surmised her education was aimed at caring for patients with 'GI' tract cancers, and she would take that as an opportunity to provide useful background.

Dr. McCall said that before her presentation she would review the materials in committee notebooks. She noted a 'Federal Register' handout, a 'CLIA Regulations' handout, a 'College of American Pathologists' handout, a letter from the vice chair of pathology at Duke who also happens to be the president of the College of American Pathologists, Dr. Stan Robboy who could not attend the committee, and a copy of the 'Duke Policy on Paraffin Block Retention and Slide Retention.' Copies of all four documents are attached to these minutes.

Dr. McCall told the committee that the handouts reflect the best practices policies and procedures outlined by Mr. Tilson. She said they already have policies and procedures in place for continuing patient care, sending materials to other institutions to continue oncologic care elsewhere, research requests and law firm requests.

Dr. McCall used the rest of her time to take the committee through a presentation about Mr. Smith, a name-changed 50 year old North Carolina native who was diagnosed with esophageal

cancer. She described his diagnosis and treatment at Duke as well as the subsequent analysis of his surgical specimens. She explained what paraffin blocks are and how they are maintained in pathology. She further detailed the case and care of Mr. Smith's son, who benefitted from the analysis of his father's paraffin archives.

Dr. McCall said that as a physician, she cares for patients by providing laboratory medicine answers. A bill that allows patients to completely take their materials out of their archives limits the options for their family and their future testing. There are policies and procedures in place to allow patients other options.

Rep. Murry thanked Dr. McCall, noted her side had 13 minutes left and said the committee would next hear from Dr. Kevin Smith.

Dr. Smith thanked Rep. Murry, Sen. Goolsby and members of the committee. He introduced himself as a practicing pathologist in Charlotte, North Carolina and the current president of the North Carolina Society of Pathologists. He said Dr. McCall's discussion was an excellent forerunner to his presentation. It offered individual detail of one case, and he would discuss the impact of the issue locally on constituents and patients that he and the committee serve.

Dr. Smith said that on behalf of the N.C. Society of Pathologists, in conjunction with the N.C. Medical Society, the College of American Pathologists and the N.C. Hospital Association, they have worked collaboratively to answer the questions posed by the LRC to further establish that indeed practices are already in place for them to assist patients and provide materials to patients when requested, when their care is either being delivered elsewhere, considered for research purposes, or in certain situations when it becomes a medical legal matter. He noted these practices have been in place for some time and that they were provided by Hugh Tilson and the N.C. Hospital Association in the committee notebooks.

Dr. Smith encouraged the committee to ask him and Dr. McCall questions pertaining to the understanding of what they do in the laboratory as part of deliberations. He said the detail included in their provided information is important and they believe performing this task in a statutory form is not in the best interests of the members of North Carolina.

Rep. Murry thanked Dr. Smith and said the committee would hear next from Sam Taylor, President of NC BIO.

Sam Taylor thanked the committee for the opportunity to speak on late notice and noted he previously had an understanding with proponents of the legislation that was no longer in place. He said NC BIO is concerned about unintended consequences. He said the definition of pathological materials in House Bill 795 is extremely broad and applies to materials whether or not patient consent has been obtained for those materials. As researchers, manufacturers and clinical trial companies they obtain that consent and they would like for it to be binding. If it is

not binding, there are serious consequences. Three areas of particular concern are academic research, clinical trials and manufacturing. Investigators often compile large libraries of samples of individual tissue specimens and compare those samples to each other and groups. From that they learn about diseases and possible treatments for disease. The integrity of those findings is based on their ability to produce those samples and to reference them later. If those samples are removed from the libraries, the value of those libraries and their findings are substantially impaired.

Mr. Taylor said that tissue samples are often captured in clinical trials. They are de-identified, and a request to return those materials will require labs to re-identify those materials and could potentially require them to withdraw those materials from the trial. These are federally regulated clinical trials and the requirements for de-identification and the integrity of the trial and preservation of the samples all go to whether or not they can manufacture a drug or get it approved. It is very important that the integrity of clinical trial samples be maintained.

Mr. Taylor said there are companies in this state that employ thousands of people manufacturing drugs from human body fluids, blood being one. Grifols, in Clayton, makes a wide variety of therapeutic agents from human blood plasma. Once that plasma goes through the manufacturing process, obviously it cannot be returned. It has gone to another patient. In addition, labs are required to keep reference samples of those materials in libraries to prove the material was safe, properly collected and properly preserved. If anything goes wrong or unexpected in treatments or drugs they can go back and try to figure out why.

Mr. Taylor summarized the bill could have an unintended impact on the areas of research, clinical trials and manufacturing and asked that his concerns be kept in mind moving forward.

Rep. Murry said the committee would hear next from Bill Graham from the law firm of Wallace and Graham.

Mr. Graham thanked Rep. Murry, Sen. Goolsby and staff and said he wanted to address the impetus for the approach to the bill. He said several years ago, 5 or more possibly, the ordinary practice was to have the patient, or advocate or attorney, sign a medical release and present that to the medical provider. The tissue or specimen being requested would be provided. He said that was the practice for years and years and years, but somewhere along the way it became his experience that the risk/loss analysts for hospitals and pathologists and Carolinas Medical Centers, who do fantastic work, said their lawyers told them that a court order is required.

Mr. Graham said he asked the basis for the asking of the court order, and he was told that is the rule. He said he asked where the rule came from and he never got an answer to that. He said he has asked and to this day he does not know, but he thinks he knows.

To describe current procedure, Mr. Graham used the hypothetical that if a family member of Sen. Brock wished to have a cancer investigated by whomever, the rule is that if his family member is at Carolinas Medical Center, he or she will need a court order from a superior court judge. He explained that you do that by going to the courthouse and file a special proceeding with the clerk. Then you have to go find a Superior Court judge and get that judge to sign that order. Then you have to present that court order to Carolinas Medical Center or Duke or whatever hospital it is.

Mr. Graham said it is time consuming, laborious, expensive and unnecessary. This actually occurred in a case when the patient was a former patient of Carolinas Medical Center, a court order was obtained, it was presented and the sheriff walked into the pathology lab, presented the court order to the pathologist, and the blocks requested for that particular individual were produced. At the end of any inquiry, investigation, case or otherwise, Mr. Graham said he thinks the bill should include that any material that has been requested or investigated be returned from whence it came. That complies with CLIA obligation and he thinks it complies with the College of American Pathologists' rules and guidelines without thwarting the substantive rights and privileges of the person requesting the material.

Mr. Graham said that in Dr. McCall's situation, that is a very important situation to realize that as medical science makes advances, material is often used in the diagnosis of genetic disorders that could lead to various diseases. He said he would be more than happy to allow a procedure where the patient requests a block of tissue, in this case esophageal tissue and the requester be provided a block or some portion of a block to investigate. The provider of medical services would keep some residual tissue for their examination on a going forward basis. He said that the material Dr. McCall presented was a good example and could be divided – some kept by the provider and some provided to the requester. There are advances being made and he does not want to impose medical science or medicine, there are a lot of great facilities in this state that provide services and advancements. He said he is not trying to thwart or impede that, he is asking that when a patient requests materials that they be allowed to present a release and obtain that in a reasonable period of time.

Mr. Graham said that Connecticut has a good law in this regard, passed in 1998, and that CLIA doesn't say anything about providing a court order. He said that the other side is suggesting patients or attorneys obtain a state court judge to allow for the release of what is otherwise a federally regulated environment. He said he has problems with that, but nevertheless that can be addressed in the bill and he would be happy to take any questions.

Rep. Murry thanked Mr. Graham and said at this point he would like to see if the committee has any discussion from members.

Discussion

Rep. Murry recognized Sen. Goolsby who said he has been reading up on the subject, possibly too much. He said he looked at the College of American Pathologists manual that deals with the effect of CLIA and would appreciate comments from presenters on its details. Sen. Goolsby asked Mr. Graham if the issue that Mr. Taylor brought up is unrelated to the concerns of the hospitals and pathologists because those patients in his descriptions signed away their rights to the materials. He asked Mr. Taylor and Mr. Graham to correct him if he's wrong, but he does not believe Mr. Graham is making any requests related to life science materials. Mr. Graham said no, and Sen. Goolsby told Rep. Murry he wanted to make sure the committee dealt with only relevant requests. He agreed that life science materials are not relevant because patients sign away their rights to access and he does not want to impede clinical trials or experiments.

Sen. Goolsby says the next issue is CLIA, and he is a practicing attorney but does not do workers compensation like Mr. Graham. He said as he looks at the CLIA requirements from the College of American Pathologists, it goes through a checklist and says that if you request the material the first thing the pathologist does is make sure it is from a legitimate, known medical provider. If they know them there are less protocol, if they don't know them they must check they are the proper carrier. Sen. Goolsby detailed the CLIA requirements listed on the handouts in committee notebooks and said they appear to him to be reasonable. He asked Mr. Graham to confirm that his problem is he is always required to get a court order for a slice of paraffin block, not just a subpoena. He asked if it is his material; my liver or my esophagus and I want it for my attorney for some reason, why can't I have it?

Mr. Graham said that going back to the esophageal example of Dr. McCall, but considering a hypothetical lung cancer, a lot of times a cancer is of an unknown primary. That happens more often than he'd like to admit, and he'd like the pathologists to speak to that. Sometimes there is a situation where a patient needs a block to get enough cells to send to a lab to see if they can determine where the primary cancer is. It's just an investigation, trying to advise the family or the person if they can determine where a cancer came from. Sometimes they can and sometimes they can't, and in situations where they cannot determine the primary Mr. Graham said he suggested the patient keep the blocks and the pathologists keep the slides. He is told to get a court order for that. They will give him slides, but sometimes he needs blocks to allow the labs he retains to do the proper testing and tell him where the cancer came from and what the cell type is. He said it is often critical to get the blocks, and sometimes there is just one block and sometimes there are a lot of blocks. Regardless of what is requested, the patient needs a court order. Mr. Graham said that is the rule, and he wasn't sure if that answered Sen. Goolsby's question.

Sen. Goolsby asked Rep. Murry for a follow-up question. Rep. Murry said he thinks there is another answer to that question, for example in some instances where they can give away the slides but not give the block. Rep. Murry asked that someone speak to that question.

Dr. McCall responded to Sen. Goolsby that in his office last summer, during a stakeholders meeting, he asked for additional data. She is the quality assurance officer at Duke and pulled additional data that may be relevant to the conversation. She said over a period of a year they evaluated how many times their paraffin blocks or slides were sent elsewhere. In a period of one year, 552 requests came to her office to send patient materials. They were usually recut slides from the blocks and were requested by another hospital or pathologist. Out of those 552 requests, Duke never required a court order. The only thing they require is a release from that patient's doctor asking to send the materials. There is no delay, it happens all the time and is reciprocated. In the same time period Duke received 47 requests from law firms, and 17 of those were from a medical litigation case involving ex-planted medical hardware such as a replacement hip or breast implants. Those patients signed a release form, so a court order was never required and those materials went to the material retrieval firm that collects for the class action litigation. Of the remaining 30 requests, those were for archival human tissue for legal purposes. Seventeen came with a letter that just requested recut sections and those were immediately processed. Eleven more were processed after Duke pathologists had a verbal discussion with the law firm on the phone about what additional testing they need and what would suffice.

Referring to Mr. Graham's discussion of unknown primary testing in cancer cases, Dr. McCall said that test requires more than one slide and can require as many as eight to twelve recut sections. That is also something they can easily provide – one paraffin block can provide up to 300 slides. It is literally a reservoir of material. Out of those 30 cases, only 2 required a court order and in both of those cases it was because the law firm requested everything Duke had. Every paraffin block, every original slide. After conversations with the law firm, Duke was unable to reach an agreement on how to share the material and required a court order. She said that is their practice and it is reflected in the best practices and principles that Mr. Tilson reviewed, as well as the College of American Pathologists regulations. She said those demonstrate that there is not a need for this legislation at this time.

Sen. Goolsby requested a follow-up question and Rep. Murry recognized him. Sen. Goolsby asked what the result of the court order was, whether all materials were turned over to the over. Dr. McCall said yes, and she has documentation to support that.

Rep. Murry recognized Mr. Tilson to make a comment. Mr. Tilson addressed Sen. Goolsby and said that in the draft principles, page 2, Section C, 'Requests from law firms and document retrieval firms,' the goal was to implement recommendation from the N.C. Hospital Association to hospitals and encourage they adopt that framework. He read from the draft principles that are

attached to these minutes. Mr. Tilson said he can't tell the committee that all hospitals are currently using the principles, but he believes that most are. He said he can tell the committee that he will distribute the principles to hospitals and his goal is to make sure they adopt the very practice Sen. Goolsby recommended.

Sen. Goolsby requested a follow-up question and asked Mr. Graham if he has looked over the N.C. Hospital Association's best practices principles. Mr. Graham said he had, and Sen. Goolsby asked what he thought about them. Mr. Graham said they are a good way to make sure there is a uniform process of procedure across the state and right now it is a little catch as catch can. He said that often the difficulty is hospitals use different procedures and treatments in different cities across the state, and he applauds the effort to standardize. He said that returning to Dr. McCall's instance when all materials were requested, there are times when a request for all the materials is made. He would encourage pathologists be allowed to keep a slide or two or three to maintain CLIA standing, unless there is something in the discovery process that mandates more tissue be collected.

Mr. Graham said he is not trying to put hospitals or risk/loss assessors in a position where they feel uncomfortable. He said he is trying to streamline a situation where they payout costs, trouble, time, effort and expense as a requester to obtain the tissue necessary to conduct an investigation on a variety of issues. He said that is what they're trying to do, not thwart medical science or impede the ability to maintain accreditation and credibility.

Rep. Murry asked Mr. Graham if he ever had a situation where he did not request all materials, he only requested slides, but was asked to get a court order. Mr. Graham said he has not faced a situation where he requested recuts and had to get a court order, it was when he asked for the blocks and needed a court order. Mr. Graham said that he requested a release but was told the lab would not accept a release signed by the patient. Mr. Graham said he suggested a subpoena and was told that could be accepted, but when he sent it over it was not sufficient. He needed a court order to obtain the request.

Rep. Murry clarified that happens when requesting an entire block and Mr. Graham said yes. Rep. Murry reminded Mr. Graham he stated he would be fine in a situation where the hospital didn't provide the entire block and retained a portion of it. Mr. Graham said absolutely, he has told pathologists that, but there are some instances when you can't cut sufficient slides out of a block. They are rare, but sometimes a patient provides very small tissue samples. Mr. Graham said he understands where the pathologists are coming from, and he wants the committee to understand he is sensitive to those issues and requirements.

Rep. Murry said he is not sure there is a way to handle legislatively a situation where all the material is required. He said you will probably need to get a court order almost every time if the tissue is so small there is no way to cut it.

Mr. Graham suggested a subpoena be acceptable in that circumstance. Rep. Murry said there are references to subpoenas in the professional relations manual of the College of American Pathologists, and they are referred to more than court orders.

Mr. Graham said he is happy to issue a subpoena in that situation if it would provide cover for the pathologists and hospitals in regards to CLIA. He said having reviewed the 2003 edition of the manual or handbook of the College of American Pathologists, he knows there is some reference made to court orders. If a pathologist receives a request from an attorney, he should notify the risk/loss analysts to consider a court order and address potential concern for a malpractice action.

Rep. Murry recognized Bill Patterson, who asked Dr. McCall what quantity of a specimen pathologists are required to retain by federal regulations, and where the regulatory authority is detailed. He also asked if the amount varies case to case and there is not an objective standard.

Dr. McCall said the limits of the regulations are in their own framework. The regulations say paraffin blocks, they don't say paraffin blocks with a specific amount of wax remaining. As pathologists, they prefer sufficient material remaining to do additional medical testing that could be warranted by the patient or their family. Striking a balance is something pathologists are given the freedom to do on an individual base with hospital policies, and they try to address the regulations that way.

Mr. Patterson asked if in the two instances the party requesting material was required to get a court order, if the hospital required the court order. Dr. McCall said that it is Duke's policy. Mr. Patterson asked if the hospital appeared in court to oppose the order. Dr. McCall said they have not opposed a court order that she is aware of. Mr. Patterson asked if Duke had no objection to an order being entered in that case. Dr. McCall said no, and in her opinion a court order does provide cover for regulatory purposes and Rep. Murry made that point.

Rep. Murry recognized Sen. Goolsby. Sen. Goolsby said he is trying to cut to the chase – if we all agree that the N.C. Hospital Association's best practice principles will satisfy everyone, why aren't we talking about adopting the best practices principles and seeing to it they are required across the board? If there are some medical operations not following those now, and we hear from our hospital association they are the best practices, why can't we simply adopt that if it complies with the federal mandates and the desires of both sides? He said it seems they may have an answer.

Mr. Graham said there was a request made to Carolinas Medical Center's laboratory network in Charlotte that required a court order for slides. The lab said they require a court order from a North Carolina judge to release any material in that case. He said as long as the requester, a patient or family member of the deceased, has an opportunity to obtain the issue, block or otherwise, he is fine with it. But to require court orders and have sheriffs serve the labs is

unnecessary in his opinion. He wants a release signed by the patient or duly authorized member of the family to be sufficient.

Rep. Murry recognized Sandy Sands, a representative for Carolinas Healthcare System. Mr. Sands said there were situations in the past brought to their attention that occurred in pathology labs and comments were made in that regard similar to Mr. Graham's. He said over the last six months they have looked at the situation very carefully with the hospital association and feel they are and will be in line with what the association developed. He said there were not hundreds of cases requiring orders, but there may have been several. Their primary goal is to make sure that the health and welfare of patients is cared for. They think with the principles set out by Mr. Tilson and the hospital association that can be done, and it is probably an issue that should have been brought to everyone's attention. They think the legislation could have unintended consequences and he appreciates Sen. Goolsby's intervention to look at the whole picture for both sides.

Rep. Murry recognized Sen. Goolsby. Sen. Goolsby said as he looks at the draft principles from the hospital association, he thinks it attempts to address concerns of plaintiffs on the back page under Section C. Sen. Goolsby read from the document, and a copy is attached to these minutes.

Sen. Goolsby said when he looks at the CLIA requirements, as Mr. Graham referenced from the physicians manual, it says that if recuts are not comparable or irreplaceable items, experts on the laboratory premises can review them and at that point it may progress into a court order issue. He said they seem to be two different things. He understands when there are medically necessary materials that are irreplaceable and not comparable and labs are being asked to give all those materials over, you could definitely be in trouble if it's a subpoena and not a court order. You may find yourself getting sued if you don't have the materials anymore. He asked Mr. Tilson if that's all the hospitals were asking for - protection through the court order when materials are irreplaceable.

Mr. Tilson said that a number of experts helped compile the draft principles. He emphasized that they were draft principles, and as they are finalized he wants to address all the issues out there as specifically as possible. He said the language included compliance with federal law, accreditation standards and evidentiary standards in order to protect medically necessary specimens. He said in an effort to address the principles Sen. Goolsby articulated, the principles in the current document may not be as strictly complaint as the final principles. He read from the draft principles, a copy of which is attached to these minutes, and said the draft document may not be complete but directionally it addresses Sen. Goolsby's concerns.

Sen. Goolsby asked Mr. Graham if he was in agreement with the best practices principles laid out by Mr. Tilson, not including the additional request of his to return the materials back to the original owner.

Mr. Graham said what he is getting at is if a requester makes a duly authorized request, however it is made; they not have to get a court order to request that a block be provided upon the duly authorized request. If it is all the material that they have, if there is just one block, then they are compromised. There might be a situation where labs could make a cut and provide the block to the requester, but that's a framework and not the 'alpha-omega,' but it is a framework. There are also stipulations that if the pathology department at Duke or Carolinas Medical Center must allow an expert to review materials, that material should go to the requester and then the expert, rather than experts traveling to the labs.

Rep. Murry recognized Mr. Tilson. Mr. Tilson said that at the risk of overstepping his knowledge, the notion of transmitting slides to other professionals is essential in patient care and it happens all the time. But when specimens are released to nonprofessionals there is a chain of custody issue and other things related to that. That raises all other types of questions about transmitting materials to labs that aren't part of patient care organizations or other affiliated organizations. Mr. Tilson said he understands what Mr. Graham is discussing but from sanctity of specimen standpoint, that would provide significant concerns to hospitals. In other words they are happy to make it available, but sending it away when they don't know where it's going, and how they will get it back and what happened to it in the interim, that is an issue.

Rep. Murry said the other labs receiving blocks, as he understands it, are also under CLIA accreditation and regulations. That actually keeps it honest within the same system, so he doesn't think a courier from law firms get paraffin blocks and put them in their backpack. When the materials are obtained, they go in a closed system to another facility subject to CLIA. Mr. Graham said that is correct. Rep. Murry said that maintains the chain of custody.

Mr. Graham said he did not want the committee to think there was a guy on a bicycle riding around downtown Raleigh with pathology in their backpack. Rep. Murry said that was the nature of the floor debate, which was a lot of fun. Mr. Graham said he does not want that to happen.

Rep. Murry recognized Sen. Purcell. Sen. Purcell referenced House Bill 795 and read from the bill regarding materials being furnished directly to patients or pathologists. He said it reads like the specimens are to go to the patients, which does not make sense because lawyers need other professionals and pathologists to take a look and see what they think.

Mr. Graham said that in a situation where an attorney requests information for medical legal examination, it typically goes from the pathologist, for example Carolinas Medical Center or Duke, to the law firm, then to the retained expert.

Sen. Purcell said as he reads it, if he wants a specimen from his appendix that was taken out, he can request that Duke give that to him and they have to give it to him.

Sen. Goolsby said he is looking at the CLIA requirements and it appears that unless the material is a recut that is not a comparable or irreplaceable item, patients ought to be given the request. Even though the CLIA requirements exist, it is your bodily material and if you wanted to frame and put on your wall, you have a right to get it. It is yours. It's not the wisest thing to do, but if it the doctor says it can be recut 300 times, unless they are not comparable or are an irreplaceable item, you should be able to get it. If it falls in that category, that's when a court order is required. He said it looks like everyone agrees. It is only when you have an evidentiary issue later, it's gone and we can't do anything, that there is an issue. He asked Dr. McCall is he is correct in that assumption.

Rep. Murry recognized Dr. McCall. Dr. McCall said she does not think it's a patient's rights issue. If your esophagus is taken out you should have that esophagus to do with what you want. In that specific situation, Duke would greatly benefit from a court order because of the health and safety risk to patients of taking a potentially Hepatitis-C infected liver specimen and storing it in their attic. Those paraffin samples are just paraffin wax, like a candle. It can melt and then the tissue is just there. They do prefer to send materials from CLIA facilities to CLIA facilities, and that's what they do for patient care. There are CLIA regulations for temperature control of paraffin blocks for all the reasons mentioned. That could violate the chain of custody. Pathological materials are not rare coins; the integrity of their makeup could be violated. Duke may not feel comfortable testing materials after they are outside of a CLIA-regulated environment.

Mr. Graham said the issue about pathological material was addressed in the House version of the bill and was taken care of there in another section. He does not want anyone's tissue to be released that has a communicable disease or something that would endanger public health. That is not what they're asking for.

Rep. Murry asked if there was further discussion or debate. Hearing none, he said the committee must come up with a report and adopt it by January 4. That means the committee is looking at a second meeting on January 4. He asked if there were any items or materials or conversations about the subject matter that members of the committee, besides what has been discussed so far, would like to be included in the committee report.

Sen. Goolsby said he encourages anyone listening online or in attendance to submit materials to be considered by email to the committee clerk. He would be happy to circulate that to everyone, and the chairs would work hard to put together a draft and get it to members for reading over the holidays.

Rep. Murry said his tentative goal is to have a draft report by December 19. He said everyone interested in influencing or including items of the conversation, they would like to have that draft report by December 19. Based on comments of that draft report, the chairs could circulate a

second draft report and the goal is to meet on Friday, January 4, 2013, to consider approval of that report. That meeting would be in the afternoon.

Rep. Murry recognized Rep. McGrady. Rep. McGrady said while the chair looks to members for comments, the sum total of what he knows about this subject he learned that afternoon. If that process is followed, he can provide meaningful input then. He is not prepared today to jump into the discussion. Rep. Murry said that is wise and he appreciates his wisdom.

Rep. Murry said the committee clerk and Sen. Goolsby would await further comment from interested parties to help build and structure a report to provide guidance for the General Assembly as a whole in the long session.

There being no further questions or comments, Rep. Murry adjourned the meeting at 4:38 p.m.

Respectfully submitted this 4th day of January, 2013,

_____ _____

Joseph A. Kyzer, Committee Clerk Rep. Tom Murry, Committee Chair